Exhibit 200

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875

EXPERT REPORT OF KARLA V. BALLMAN, PhD, FASCO

A. Summary of Opinions

I have been asked to review the proposed thresholds for valsartan, including combination valsartan, containing NDMA and/or NDEA impurities ("affected valsartan") that would allegedly create a statistically significant increased risk of cancer in individuals who consumed affected valsartan.[1] Specifically, I was asked to determine whether there is evidence that supports the use of the proposed thresholds based upon the expert reports of Drs. Panigrahy and Madigan, and how the proposed thresholds were derived.

It is my opinion that the Plaintiffs' basis for establishing the proposed thresholds is subjective, arbitrary, unscientific, and not transparently derived from the available data. Moreover, there is evidence that most of the implicit assumptions underlying the proposed thresholds are invalid, and there is no evidence for a single amount of lifetime cumulative exposure for NDMA or NDEA that is associated with a meaningful increased risk of cancer.

[1] *See* Plaintiffs' Memorandum of Law in Support of the Medical Monitoring Plaintiffs' Motion for Class Certification, *Valsartan Products Liability Litigation*, November 10, 2021, Dkt. 1750 ("Medical Monitoring Brief"); Plaintiffs' Third Amended Medical Monitoring Class Action Complaint, *Valsartan Products Liability Litigation*, November 1, 2021, Dkt. 1709 ("Complaint").

Each of these opinions, which are offered pursuant to Rule 26 of the Federal Rules of Civil Procedure, are given to a reasonable degree of scientific certainty and are based on the methods and procedures of science, materials, and literature I have reviewed in connection with this litigation, my knowledge of recognized scientific principles, and methodology reasonably relied upon by members of my profession, as well as my education, training, knowledge, and experience.

B. Expert Background and Qualifications

I am the Division Chief and Professor of Biostatistics at Weill Cornell Medicine. Before joining Weill Cornell Medicine, I was at the Mayo Clinic in Rochester Minnesota for approximately 16 years. A summary of my previous positions can be found in my Curriculum Vitae, which can be found in Appendix A.

I have been a co-author of more than 225 manuscripts, most of them in the area of oncology. My current collaborative research interests include clinical trials, mostly in oncology, and the development of biomarkers that can be used to determine which patients would benefit from specific treatments. In the past, I have also collaborated on a number of observational, epidemiology studies. Professionally I have been or am a member of several National Cancer Institute committees, including the Breast Cancer Steering Committee as well as the Brain Malignancies Steering Committee. I have been an Associate Editor and subsequently Deputy Editor for the Journal of Clinical Oncology, one of the most respected oncology journals. I currently serve as a grant reviewer for the National Institutes of Health Kidney, Nutrition, Obesity and Diabetes Study Section (KNOD) study section. As part of this, I review approximately 20 grant proposals per year. These proposals are grant applications and the epidemiological research designs and approaches reviewed in KNOD include cohort, case-control, prospective, longitudinal, retrospective, clinical trial, cross-sectional, surveillance, genetics, epigenetics, genomics,

transcriptomics, gene-environment interactions, genome-wide association studies, metabolomics, molecular genetics, and Omics technologies. In 2021, I was named as a Fellow of the American Society of Clinical Oncology. In addition, I have served on several other grant review committees including the Damon Runyon Clinical Investigator Award, the Department of Defense awards, and the Conquer Cancer awards.

In the past 4 years, I have testified at two trials. One was a patent case for abiraterone acetate in the treatment of prostate cancer in the United States and the second was for a similar trial in Canada. In both cases, I was an expert witness for the defense (Janssen Oncology). I have testified as part of depositions a total of 3 times as an expert witness: once for Janssen Oncology (US), once for Eli Lilly in a case of Cialis and risk of melanoma, and once for Johnson and Johnson with respect to talc powder exposure and the risk of ovarian cancer.

My fees charged in connection with this engagement are consistent with my normal practice. My rate for reviewing materials, preparing reports, and deposition and trial testimony is $400 per hour. This compensation is not contingent on the nature of my findings and opinions or on the outcome of this litigation.

I understand that the Defendants in the above-referenced litigation may rely upon my expert testimony at trial.

A list of the materials I relied upon in preparing this report is attached as Appendix B.

C. Summary and Analysis of Plaintiffs' Medical Monitoring Claims

1. Proposed Thresholds

The information regarding Plaintiffs' proposed thresholds is taken from the Plaintiffs' Medical Monitoring Brief.[2] It states: "The determination of whether the Class Member consumed

[2] Medical Monitoring Brief, 8-9.

a Lifetime Cumulative Threshold sufficient for Class membership is based on dosage, API manufacturer, and time period," and then lists eligibility criteria for determining class membership, summarized for purposes of this report in Table 1.[3]

Table 1: Class member determination criteria

Scenario	Dose	ZHP API	Hetero API	Mylan and/or Aurobindo API
A	320 mg	3 months	18 months	54 months
B	160 mg	6 months	32 months	108 months
C	80 mg	12 months	64 months	216 months
D	40 mg	24 months	128 months	432 months

There are four scenarios provided by Plaintiffs based on the dose of valsartan per tablet. It appears that Scenarios B, C, and D may be derived from Scenario A. The time periods provided for scenarios B, C, and D are evidently multiplied by the reciprocal for the amount the dose was reduced from Scenario A. For example, a dose of 160 mg is half that of 320 mg and so the time an individual would have to take ZHP API derived medication at dose 160 mg to achieve the Lifetime Cumulative Threshold would need to be double that for a 320 mg dose, which is 3 months × 2 = 6 months. Note that this is true for all values in the table except for the column of Hetero API. The amount of time for a 320 mg dose is 18 months but the time for a 160 mg dose is 32 months, which is not the expected 36 (= 2 × 18) months. However, for scenario C, where the dose is half that of scenario B, the time stated is 2 times that for B (e.g., 32 months × 2 = 64 months), which is what is expected. Likewise, for scenario D, where the dose is half that of scenario C, the time stated is 2 times that for C (e.g., 64 months × 2 = 128 months), which is what is expected. Based on this, I assume for the remainder of my report that that the 18 months for Hetero API is a typo and should

[3] Medical Monitoring Brief, 8-9.

be 16 months, though it could also be that Plaintiffs intended Scenarios B-D for Hetero API to be 36, 72, and 144 months, as it is not clear how Plaintiffs derived the number of months for Scenario A, as I explain in more detail below.

Plaintiffs also claim that class membership could be based on a combination of products from different manufacturers to obtain the same cumulative exposure. The example provided in Plaintiffs' Medical Monitoring Brief is for an individual prescribed 320 mg of valsartan. To achieve the Lifetime Cumulative Threshold ("LCT") for class membership, an individual could consume two months of the product derived from ZHP API, which is two-thirds of the cumulative LCT for ZHP API. The remaining one-third of the amount required to achieve the LCT could, according to Plaintiffs, be achieved by the individual consuming six months' worth of product derived from Hetero API, which is one-third of the needed 18 months for consumption of this product to achieve LCT.

There are several implicit—and in multiple instances scientifically invalid—assumptions made with respect to the class membership criteria in Table 1. The membership criteria appear to assume, among other things:

- It is possible to determine for everyone who consumed valsartan containing an NDMA- and/or NDEA- impurity whether they have met the criteria as listed.
- There is variability in the amount of NDMA and/or NDEA found among the different manufacturers of valsartan.
- Despite variability between manufacturers, the amount of NDMA and/or NDEA for a manufacturer is constant, meaning it does not vary from lot to lot.
- The amount of NDMA and/or NDEA in the manufacturer's API formulation is the same as in the tablet an individual would consume, that is the finished product.
- There is a bright-line threshold for lifetime cumulative exposure that is associated with a meaningful increase in cancer risk.
- The lifetime cumulative threshold is the same for all persons and all cancers of interest.

I will address each of the assumptions above, and will try to replicate the proposed monitoring thresholds in Table 1 based on the information contained in the expert reports of Drs. Panigrahy and Madigan, which Plaintiffs cite as the basis for the stated thresholds for medical monitoring class membership.

2. Determination of Class Membership

Plaintiffs state that the information needed to apply the criteria for medical monitoring class membership in Table 1 is available.[4] According to Plaintiffs, the required information will be obtained by examining pharmacy and prescription records and by reference to the unique 10-digit NDC issued for all generic drug products.[5] As such, this information will purportedly provide the dose amount of valsartan, the form of the dose product, and the package size.[6] Plaintiffs claim that from this information, it is possible to construct a consumption record for proposed class members.[7] Note, for the latter to be true, Plaintiffs assume not only the availability of this product identification information, but also that individuals consume the entirety of their prescribed medication.

I have no opinion as to whether Plaintiffs can in fact obtain and utilize the information described to identify for each patient in the proposed class the dose of valsartan they were prescribed, the manufacturer of the medication, and the duration of their consumption (if individuals take all the prescribed medication). I also have no opinion as to whether, assuming the information described is available, it is in fact feasible to do what Plaintiffs describe. Even assuming, however, that Plaintiffs can obtain and utilize pharmacy records in the manner

[4] Complaint, ¶ 540; Medical Monitoring Brief, 9.

[5] Medical Monitoring Brief, 9.

[6] Medical Monitoring Brief, 9.

[7] Medical Monitoring Brief, 9-10.

described, what they cannot do from the information provided is identify whether the proposed class members in fact consumed their prescribed valsartan, and, if so, whether the consumed valsartan contained an NDMA and/or NDEA impurity. The NDC does not identify the lot number of the prescription, not all lots of valsartan were recalled, and not all tested lots from the same manufacturer contained the same levels of detected NDMA or NDEA.

3. Variability in NDMA and/or NDEA Impurity Levels Among Different Manufacturers

The thresholds in Table 1 assume that there are differing amounts of NDMA and/or NDEA among different manufacturers of valsartan. I agree with the assumption that there are different levels of NDMA and NDEA impurities across the different valsartan manufacturers. As a result, Plaintiffs' acknowledge that their proposed LCTs must vary across the different manufacturers to account for differing levels of NDMA and/or NDEA detected in different manufacturers' valsartan. The necessary implication of this acknowledgment is Plaintiffs' recognition that their proposed LCTs must vary based on varying levels of exposure to NDMA and/or NDEA.

4. Plaintiffs Assume No Variability in NDMA and/or NDEA Impurity Levels for the Same Manufacturer

The thresholds in Table 1 implicitly assume—incorrectly and without scientific basis or foundation—that there is no within-manufacturer variability in the levels of amounts of NDMA and/or NDEA impurity levels. That is, Plaintiffs assume every batch of every valsartan product from the same manufacturer contained the same identical amounts of NDMA or NDEA. There is only a single time value for each manufacturer within a given valsartan dose level. Yet, looking at

the test results Dr. Panigrahy cites, and the FDA's published testing results, there is clear variability among the different lots within a given manufacturer.[8]

I disagree with the implicit assumption that there is a constant level of NDMA or NDEA within a manufacturers' affected valsartan. The amount of NDMA or NDEA impurity clearly depends on the product lot. Plaintiffs' implicit assumption for the proposed thresholds for class membership is not valid. It is a basic tenet of toxicology that the "dose makes the poison." Plaintiffs leave unanswered the central question, which is, "how many nanograms or micrograms of NDMA and NDEA do they believe is necessary to create a statistically significant increased risk of cancer?" Instead, they attempt to use the length of time a patient used each manufacturer's valsartan-containing medications as a proxy for dose. But, because there is wide lot-by-lot variation in the level of impurities detected in a manufacturer's valsartan-containing medication, the comparison is invalid. As a result, individual Plaintiffs will not be able to establish the quantity of the NDMA and/or NDEA impurity contained in the valsartan that they consumed, if any.

5. Plaintiffs Assume Similar Levels of Impurities in API Product and Finished Dose Product

The thresholds in Table 1 further implicitly assume the levels of impurity in affected valsartan API are the same as what would be found in the finished dose product, which is the valsartan tablet that is consumed by an individual. The thresholds in Table 1 are reported in terms of API levels and for these to be valid, there needs to be evidence that the impurity levels are the same between API formulation and the tablet that is consumed by an individual. Reviewing the manufacturer's testing data, it is clear this is not the case. For example, for Aurobino Valsartan

[8] *U.S. Food & Drug Administration*, "Laboratory analysis of valsartan products," available at https://www.fda.gov/drugs/drug-safety-and-availability/laboratory-analysis-valsartan-products; Rule 26 Expert Report of Dipak Panigrahy, MD, *Valsartan, Losartan, and Irbesartan Products Liability Litigation.* July 6, 2021 (hereafter, "Panigrahy Report"), 90.

320 mg lot (packing batch number VUSD17010-A / vendor batch number 1711117292 / API Lot # G1P-18-654096) the amount of NDEA detected in the API batch was 0.096 μg, and the amount detected in the corresponding finished product batch was 0.048 μg, which is a two-fold reduction in the level of impurity. This is not an isolated case but in general, there appear to be lower levels of impurity in the finished product (tablet that will be consumed) compared to the API.[9]

I disagree with the implicit assumption that the level of impurity in the affected valsartan API formulation is the same as that in the finished product, which is the tablet an individual will ingest.

6. Lack of an Identifiable Bright Line for Lifetime Cumulative Threshold for Increased Cancer Risk

The dietary and occupational observations studies cited by Drs. Madigan and Panigrahy have considerable variability in effect sizes for the strength of association between NDMA and cancer risk. This is clear from Table 1 of Dr. Madigan's report.[10] The lifetime cumulative exposure ("LCE") levels for NDMA levels reported within a single cancer type vary with respect to whether the result is statistically significant and the amount of NDMA LCE. For lung cancer, there are three studies, with the Goodman study separating males and females so there are four reported levels. Three of the studies have statistically significant results. The LCE values range from 2338 μg to 6114 μg (after correcting the value of 16363 μg for the Goodman study to 2338 μg, as per Dr. Madigan's deposition). Furthermore, the 2338 μg LCE from the Goodman study is statistically significant and the higher LCE level (3343 μg) from the Loh study is not. Similar variability in the proposed LCE levels occurs for some of the other cancers in the table. With respect to the

[9] *See, e.g.,* MYLAN-MDL2875-00895544, TEVA-MDL2875-00765603, PRINSTON00075797, SOLCO00028261, APL-MDL 2875-0139456, Auro-MDL 2875-0104586, Auro-MDL 2875-0113985, HETERO_USA000025245.

[10] Rule 26 Expert Report of David Madigan, PhD, *Valsartan, Losartan, and Irbesartan Products Liability Litigation.* July 6, 2021 (hereafter, "Madigan Report"), 7.

dietary studies, Dr. Madigan observes, "[t]here was, however, considerable between-study heterogeneity. LCE's across component studies ranged from 1412 μg to 6607 μg."[11] There are also substantial differences between what is reported as LCE between the dietary studies and the occupational exposure study. If one employs the LCE definition proposed by Dr. Madigan to the occupational exposure studies, the LCE would use the lower bound of NDMA daily level in the highest group. This would yield a total cumulative exposure value of 23,247 μg, which is several times higher than the 6607 μg for the maximum in the dietary studies. Given the range of LCE values reported in Dr. Madigan's report, there is not a clearly identifiable threshold.

Dr. Panigrahy also provides a summary of cumulative NDMA associated with an increased risk of cancer. However, he states "[w]hile these are examples of cumulative NDMA exposures that resulted in a statistically significant increased risk of cancer, they should not be considered as bright line thresholds that are necessary to meet in order for there to be a causal relationship between NDMA exposure and cancer response."[12]

With regard to NDEA, the data is even more problematic since there is only a single study that reports an association between NDEA level and incidence of cancer that is cited by Drs. Madigan and Panigrahy. It is the Zheng, et al. study, and the LCE computed by Dr. Madigan that has a statistically significant association with pancreatic cancer is 4536 μg based on the lower bound of the highest dose group. (I note in his conclusions he deviates from this and uses as the LCE the lower bound of the second-lowest group, which yields an LCE of 2520 μg.) It cannot be assumed that studies relating to NDMA can be used to assess hazard or risk with respect to NDEA. Indeed, genotoxicity and carcinogenicity vary greatly within the class of impurities known as

[11] Madigan Report, 3.

[12] Panigrahy Report, 90.

nitrosamines, with some (such as those found in cigarette smoke) designated by IARC as Class 1 and others falling in lower classifications. But even assuming studies concerning NDMA have some bearing on the risk associated with NDEA, given the variability in the reported NDMA LCE values in the dietary studies found to be statistically significant, it is likely that there would be similar variability in the NDEA levels had more studies measured NDEA. Dr. Panigrahy also does a calculation of a lifetime exposure of NDEA that is associated with increased cancer risk and his level is 3942 μg. He again observes " . . . *they should not be considered as bright line thresholds that are necessary to meet in order for there to be a causal relationship between NDMA exposure and cancer response*."[13] It is also telling that for a single study of NDEA there are three different LCEs proposed among the two experts, which again signifies that the lack of an identifiable bright line for a cumulative threshold.

The FDA does propose regulatory intake (AI) limits of daily consumption of NDMA and NDEA in valsartan. The daily levels of NDMA and NDEA impurity in valsartan tablets deemed to be safe by the FDA are 0.096 μg (equivalent to 3 ppm in a 320 mg tablet) and 0.0265 μg (0.082 ppm in a 320mg tablet), respectively. However, this cannot be interpreted as the level beyond which there is a meaningful increased risk of cancer. This value represents a linear (no-threshold) extrapolation from animal data and is estimated to correspond to an increase in cancer risk of not more than 1 in 100,000. This risk is negligible considering a lifetime cancer risk for an individual of 1 in 3.[14]

[13] Panigrahy Report, 90 (emphasis supplied).

[14] Snodin DJ, Elder DP. Short commentary on NDMA (N-nitrosodimethylamine) contamination of valsartan products. Regul Toxicol Pharmacol. 2019, Apr;103:325-329. doi: 10.1016/j.yrtph.2019.01.007. Epub 2019 Jan 8. PMID: 30629969.

I disagree that there is an identifiable bright-line threshold for lifetime cumulative exposure for either NDMA or NDEA ingested via affected valsartan. If a such a threshold exists, it would need to be such that it can be determined by different experts when presented with the same scientific studies. Dr. Panigrahy and Dr. Madigan do not independently arrive at the same threshold value for NDMA or NDEA. Indeed, Dr. Panigrahy concedes that his review of the dietary studies did not result in the determination of a "bright line" threshold. (Panigrahy Rep. p. 90.)

7. Plaintiffs' Proposed Lifetime Cumulative Threshold is the Same for All Cancers

Plaintiffs' Medical Monitoring Brief appears to indicate that if an individual meets the criteria proposed for medical monitoring class membership, they would be monitored for a variety of different cancers. This invokes the implicit assumption that there is a common threshold shared by the different cancers. In Dr. Madigan's conclusions, he gives different LCE values for the different categories of cancers.[15] I am not aware of any Plaintiffs' expert who has established—or even attempted to establish—to any degree of scientific certainty that the proposed thresholds for each cancer category are the same.

I disagree with the implicit assumption that there is a common threshold for the different types of cancer. Plaintiffs offer no scientific support for this assumption.

8. Replication of the Proposed Lifetime Cumulative Thresholds for medical monitoring

When trying to replicate the thresholds, I focused on Scenario A of Table 1 (using a Hetero threshold of 16 months to correspond with the reported levels in Scenarios B-D) since the other scenarios can be derived from it. Specifically, I assume that the daily dose of valsartan consumed

[15] Madigan Report, 8-9.

by an individual is 320 mg. The components necessary for the determination of the proposed thresholds are

- The dose of valsartan consumed;
- The amount of NDMA and/or NDEA impurity contained in the tablet for each manufacturer (assuming the same level of exposure for different drug lots, which is not the case); and
- The lifetime cumulative exposure amount of NDMA and/or NDEA that is associated with a meaningful increased risk of cancer in a human being.

With this information, it would be straightforward to set a threshold, assuming the erroneous assumptions discussed above were true. Both Drs. Panigrahy and Madigan perform these calculations. For example, Dr. Madigan determines "[a]t a contamination level of 20 μg/day, the number of years of valsartan consumption needed to reach the total exposure equivalents in Hidajat is 1.0 year for Q1, 2.0 years for Q2, and 3.2 years for Q3."[16] His calculations of the total exposure levels are provided in a preceding paragraph, and to determine the length of time for the daily ingestion of affected valsartan, the cumulative threshold quantity of NDMA is divided by the daily exposure amount. Dr. Panigrahy performs a similar calculation in his report where he finds that for a patient taking 320 mg per day of ZHP valsartan with an average impurity level of 65.1 ppm, the patient would reach a cumulative NDMA exposure for the second quartile in the Hidajat, et al. study[17] (which he states is 5990 μg) in 10 months.[18]

Critically, Plaintiffs' proposed threshold is only expressed in the length of time required for daily ingestion of an affected 320 mg valsartan tablet for each manufacturer. The assumed

[16] Madigan Report, 8.

[17] Notably, the Hidajat study involved occupational inhalation exposure of NDMA and other carcinogens to factory workers in the UK rubber industry.

[18] Panigrahy Report, 89.

amount of NDMA and/or NDEA impurity in the 320 mg tablet is not provided. In addition, the LCE level needed to reach a meaningful increase in cancer risk is not given. Plaintiffs' Medical Monitoring Brief references the Madigan and Panigrahy expert reports as the justification for the thresholds. Yet, there are two significant unknowns based on these reports: (i) the assumed level of NDMA and/or NDEA impurity in the 320 mg valsartan tablet (there will be a different level for each manufacturer and by lot/batch), and (ii) the LCE associated with each type of cancer (this would be the same for each manufacturer). Upon reviewing the two expert reports, I was unable to find a clearly stated LCE level associated with a meaningful increase in cancer risk. In addition, I was unable to find a single value for the NDMA and/or NDEA impurity amount for a 320 mg valsartan tablet for each manufacturer. As discussed above, there are multiple LCEs referenced in the Madigan and Panigrahy reports, and multiple different levels of NDMA and/or NDEA impurity associated with each manufacturer and each manufacturer's lot/batch.

In the absence of clearly specified values, I tried to determine the impurity amounts for NDMA and NDEA in 320 mg of valsartan using the LCEs in Dr. Madigan's report and the time thresholds proposed for each manufacturer proposed by the Plaintiffs. I would note at the outset that any statistical methodology requiring a reviewer to "back in" to the data in this manner—that is, to use the outcomes to try determine the inputs—is at best incomplete and likely invalid. Putting that aside, Table 3 contains the daily exposure levels in terms of μg and ppm by manufacturer for NDMA, assuming a 320 mg daily dose.

To illustrate how the calculations were performed, I step through it for the ZHP API and gastric cancer.

- to get the daily μg amount, divide 1962 μg by 91.3 days
- to get the ppm, multiply the daily amount by 1000 ng/μg and divide by 320 mg

Table 3. Determination of the amount of NDMA impurity in 320 mg valsartan tablet by manufacturer and cancer LCE

Cancer	**LCE***	**ZHP API 3 mo (91.3 days)**	**Hetero API 16 mo (487 days)**	**Mylan/Aurobindo API 54 mo (1643.6 days)**
gastric[1]	1962 μg	21.5 μg 67.2 ppm	4.0 μg 12.6 ppm	1.3 μg 3.7 ppm
lung[1]	2338 μg	26.5 μg 80.0 ppm	4.8 μg 13.3 ppm	1.4 μg 4.4 ppm
esophageal[1]	4235 μg	46.4 μg 145.0 ppm	8.7 μg 27.2 ppm	2.6 μg 8.1 ppm
rectal[1]	3343 μg	36.6 μg 114.4 ppm	6.9 μg 21.5 ppm	2.0 μg 6.4 ppm
all[2]	7514 μg	82.3 μg 257.2 ppm	15.4 μg 48.2 ppm	4.5 μg 14.3 ppm

* From Madigan expert report
[1]from dietary exposure studies
[2]from occupational exposure studies

Comparing these values to the level of impurity cited in Dr. Panigrahy's report there is no match except for ZHP API, but only for gastric cancer if we take the average of the midpoints for ZHP (which is approximately 66.4 ppm). Further, neither Mylan nor Aurobindo's NDMA impurity levels appear to have exceeded FDA's acceptable intake limits.

Doing the same exercise for NDEA and pancreatic cancer (obtained only from a single dietary study), we get Table 4.

Table 4. Determination of the amount of NDEA impurity in 320 mg valsartan tablet by manufacturer and cancer LCE

Cancer	**LCE***	**ZHP API 3 mo (91.3 days)**	**Hetero API 16 mo (487 days)**	**Mylan/Aurobindo API 54 mo (1643.6 days)**
pancreatic	2520 μg	27.6 μg 86.3 ppm	5.2 μg 16.2 ppm	1.5 μg 4.8 ppm

Again, other than ZHP API, none of the other levels of impurity for any manufacturer fall in the range found in Dr. Panigrahy's report. Indeed, Dr. Panigrahy's presumed levels are much higher those observed in Defendants' testing data.

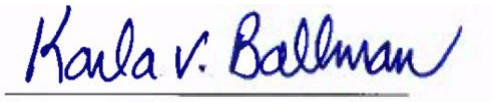
Based on my analysis, I was unable to identify any reliable data points to support Plaintiffs' LCTs for each manufacturer's valsartan drug, each cancer type, and each proposed LCT. Plaintiffs' proposed LCTs to determine eligibility for membership in the medical monitoring class consequently lack any verifiable basis or identifiable support.

D. Conclusion

There is no obvious support for the Plaintiffs' proposed LCTs for medical monitoring. The proposed thresholds erroneously assume there is no variability in NDMA and/or NDEA impurity levels for a manufacturer, there are similar levels of impurity in API product and finished product, there is an identifiable bright line for an LCT associated with increased cancer risk, and that the LCT is the same across different cancer types. As discussed above, there is no support for these assumptions in the expert reports from Drs. Madigan and Panigrahy, which are cited as the basis for the proposed thresholds. Rather, there is evidence in the reports that these assumptions are invalid. The most important assumptions that need to be met are that there is a single NDMA and/or NDEA impurity amount for each manufacturer for the finished product consumed by all individuals, and that there is an identifiable LCE for NDMA and/or NDEA that is associated with a meaningful increased risk of cancer. There is evidence that the amount of NDMA and/or NDEA impurity varies by finished product lot so that a single amount for each manufacturer's finished product does not exist. In addition, two Plaintiffs' experts with access to the same data sources did not obtain or identify a single LCE associated with a meaningful increased risk of cancer. In fact, Dr. Panigrahy states that such a threshold does not exist. Furthermore, the LCE amounts calculated by the two experts do not match each other and differ depending upon the type of exposure (diet or occupational), and type of cancer.

Finally, using values found in Dr. Panigrahy's and Dr. Madigan's expert reports, I was unable to match the LCTs proposed by the Plaintiffs. The likely explanation is that there are two unknowns associated with the LCTs proposed by the Plaintiffs, which are expressed as the duration of consumption of valsartan by dose and manufacturer: the amount of impurity in the valsartan dose, and the LCE necessary for a meaningful increased risk of cancer. Essentially, there is one equation with two unknowns, and for each unknown, there are many possible values found in the expert reports. This yields a multitude of different combinations that would need to be tried to match the proposed LCTs.

Based on this, it is my opinion that the Plaintiffs' basis for establishing the proposed thresholds is subjective, arbitrary, unscientific, and not transparently derived from the available data.



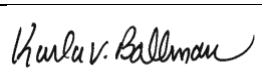
Karla V. Ballman, PhD, FASCO

January 12, 202

APPENDIX A

SECTION 1.01 WEILL CORNELL MEDICAL COLLEGE *CURRICULUM VITAE* FORM

(REQUIRED FORMAT)

Signature (required):	
Version date:	January 5, 2022

A. GENERAL INFORMATION

Required Information:

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Beeper:	N/A
Work Email: Personal Email:	kab2053@med.cornell.edu kvballman@gmail.com
Citizenship:	USA
If not a U.S. Citizen, do you have:	Immigrant visa (green card)? Non-immigrant Visa? Type:

Optional Information (not required but helpful):

Birth date:	11/14/1960
Birth place:	St. Cloud, MN

Marital status:	Divorced
Race/Ethnicity:	Caucasian

B. EDUCATIONAL BACKGROUND

1. Academic Degree(s): B.A. and higher; institution name and location; dates attended; date of award. Expand the table as needed.

Degree (abbreviation)	Institution Name and Location	Dates attended	Year Awarded
B.A.	Macalester College St. Paul, MN	9/1979 to 5/1983	1983
Scientiæ Magister (S.M.)	Massachusetts Institute of Technology Cambridge, MA	9/1985 to 6/1991	1989
Ph.D.	Massachusetts Institute of Technology Cambridge, MA	9/1985 to 6/1991	1991

2. Post-doctoral training (include residency/fellowships): In chronological order beginning with post-doctoral training positions; include full titles, ranks and inclusive dates held. Expand the tables as needed.
   N/A

3. Continuing Medical Education Courses/Certificates
   N/A

4. Other Educational Experiences
   N/A

C. LICENSURE, BOARD CERTIFICATION, MALPRACTICE

1. Licensure: Every physician appointed to the Hospital staff, except interns, and aliens in the US via non-immigrant visas, must have a New York State license or a temporary certificate in lieu of the license.
   N/A

2. Board Certification
   N/A

3. Malpractice Insurance

N/A

D. PROFESSIONAL POSITIONS AND EMPLOYMENT

1. Academic positions (teaching and research)

Title	Institution name and location	Dates held
Assistant Professor of Mathematics and Computer Science	Macalester College St. Paul, MN	8/1991 to 6/1999
Lecturer of Statistics	University of Auckland Auckland, New Zealand	1/1994 to 7/1996
Assistant Professor of Biostatistics	Mayo Clinic College of Medicine Rochester, MN	12/1999 to 7/2001
Associate Professor of Biostatistics	Mayo Clinic College of Medicine Rochester, MN	7/2001 to 10/2007
Adjunct Associate Professor of Biostatistics	University of Minnesota Minneapolis, MN	9/2007 to 7/2015
Adjunct Associate Professor	Biomedical Informatics and Computation Biology, University of Minnesota Rochester Rochester, MN	9/2010 to 7/2015
Professor of Biostatistics	Mayo Clinic College of Medicine	11/2014 to 7/2015
Professor of Healthcare Policy and Research Tenure awarded (11/2016)	Weill Cornell Medical College New York, NY	7/2015 to present

2. Hospital positions (e.g., attending physician)

N/A

3. Other Employment

Title	Institution name and location	Dates held
Actuarial Trainee	Minnesota Mutual Life Insurance Company St. Paul, MN	1983 to 1985
Consultant	AT&T Bell Labs Software Production Research Naperville, IL	1991 to 1994
Research Associate	Division of Biostatistics, Department of Health Sciences Research, Mayo Clinic Rochester, MN	1999 to 2002
Senior Research Associate	Division of Biostatistics, Department of Health Sciences Research, Mayo Clinic Rochester, MN	2002 to 2004
Senior Associate Consultant	Division of Biostatistics, Department of Health Sciences Research, Mayo Clinic Rochester, MN	2004 to 2007

Senior Associate Consultant	Division of Biomedical Informatics Department of Health Sciences Research, Mayo Clinic Rochester, MN	2005 to 2007
Group Statistician	American College of Surgeons Oncology Group (ACOSOG) Statistics and Data Center Rochester, MN	2006 to 2014
Chair	Division of Biostatistics, Department of Health Sciences Research, Mayo Clinic Rochester, MN	2006 to 2008
Consultant	Division of Biostatistics, Department of Health Sciences Research, Mayo Clinic Rochester, MN	2007 to 2008
Consultant	Division of Biomedical Statistics and Informatics, Department of Health Sciences Research, Mayo Clinic Rochester, MN	2008 to 2015
Associate Editor	Journal of Clinical Oncology	2010 to 2017
Deputy Editor	Journal of Clinical Oncology	2017 to present
Consultant	Department of Surgery, Mayo Clinic Rochester, MN	2012 to 2015
Director of Biostatistics	Alliance Statistics and Data Center Rochester, MN	2013 to 2015
Division Chief of Biostatistics and Epidemiology	Healthcare Research and Policy Weill Cornell Medical College New York, NY	07/2015 to present

E. EMPLOYMENT STATUS (current or anticipated)

Name of Employer(s): Weill Cornell Medical College
Employment Status (choose one, delete the others): Full-time salaried by Weill Cornell

F. INSTITUTIONAL/HOSPITAL AFFILIATION

N/A

G. PERCENT EFFORT AND INSTITUTIONAL RESPONSIBILITIES

WCMC ANTICIPATED % EFFORT	(%)	Does the activity involve WCMC students/researchers? (Yes/No)
TEACHING	20%	yes
CLINICAL	0%	
ADMINISTRATIVE	40%	no
RESEARCH	40%	yes
TOTAL	100%	

H. INSTITUTIONAL RESPONSIBILITIES

1. Teaching (e.g., specific teaching functions, courses taught, dates: For guidance refer to Teaching Metrics table. Report your teaching activities in the 4 areas of teaching shown below. To provide a more detailed teaching report, use the Teaching Activities Report template or Educator Portfolio template (strongly encouraged). Refer to it here as an attachment (e.g., see attached), and attach it to the CV.

Didactic teaching: (e.g., lectures, continuing medical education courses, grand rounds, professional development programs, seminars, tutorials)	
Protocol Development (tutorial leader, Mayo Clinic College of Medicine) Health Sciences Grand Rounds	Dates 2008-2012
Mentorship: (e.g., mentor for medical student, graduate student, resident, clinical or postdoctoral research fellow or junior faculty projects; service as graduate student thesis advisor or committee member)	
8 M.S. candidates in the Clinical Research Master's degree program (Mayo Clinic College of Medicine) Served on five M.S. thesis committees for M.S. candidates in the Clinical Research Master's degree program (Mayo Clinic College of Medicine) Thesis advisor to 4 students in the Biomedical Informatics and Computational Biology M.S. degree program	Dates 2004-2015 2004-2015 2012-2015
Clinical teaching: (e.g., teaching in the clinic or hospital including bedside teaching, teaching in the operating room, preceptor in clinic)	
	Dates
Administrative teaching leadership role: (e.g., residency or fellowship director, course or seminar director or co-director)	
Probability and Mathematical Statistics (course director, Macalester College) Introductory Statistics (course director, Macalester College) Mathematical Modeling (course director, Macalester College) Calculus II (course director, Macalester College) Calculus III (course director, Macalester College) Applied Probability (course director, Macalester College) Mathematical Statistics Stochastic Methods in Management Science (course director, University of Auckland)	Dates 1991 1991, 1992 1991, 1992 1992 1992 1992-1998 1993-1999 1994-1996 1994-1996

Decision Analysis (course director, University of Auckland)	1994-1996
Data Analysis with R (course director, University of Auckland)	1994-1995
Statistics Minor Curriculum Development (Macalester College)	1995-1996
Elementary Statistics (course director, Macalester College)	1996-1998
Linear Algebra (course director, Macalester College)	1996
Senior Capstone (course director, Macalester College)	1997-1999
Applied Multivariate Statistics (course director, Macalester College)	1998
Differential Equations (course director, Macalester College)	1998
Experimental Design and Data analysis (course director, Macalester College)	1998
Introductory Statistical Method I (course director, Mayo Clinic College of Medicine)	1999
Special Topics in Health Sciences Research (course director, Mayo Clinic College of Medicine)	2000-2003
Introductory Statistics Methods II (course director, Mayo Clinic College of Medicine)	2002, 2005
Clinical Trials (course director, Mayo Clinic College of Medicine)	2003-2004
Introduction to Biostatistics (course director, Executive MBA/MS program, Weill Cornell Medicine)	2010, 2011
Biostatistics I (course director, Biostatistics and Data Science MS program, Weill Cornell Medicine)	2017-present 2018-present

2. Clinical care (duties, dates: To document clinical activities use the table below or, to document extensive clinical activities use the Clinical Portfolio template (strongly encouraged). Refer to it here as an attachment and attach it to the CV.
   N/A

3. Research (duties, dates): Summarize research activities in the table below. Provide key contributions, and annotate key grants and publications or use a Statement of Key Contributions. Refer to it here and attach it to the CV.

Research Activity / Key Contributions	Dates
See Statement of Key Contributions	

4. Administrative Activities (duties, dates): Describe administrative activities in the table below. To document administrative activities more extensively use a supplemental statement, refer to it here and attach it to the CV.

Administrative Activity	Date
Education Committee Member (Health Sciences Research, Mayo Clinic)	2000 to 2002
Education Committee Chair (Health Sciences Research, Mayo Clinic)	2002 to 2007
Education Committee Member (Clinical Research Training Program, Mayo Clinic)	2001 to 2006
Executive Committee Member (Clinical Research Training Program, Mayo Clinic)	2001 to 2005
Master's Examination Committee Member (Clinical Research Training Program, Mayo Clinic)	2002 to 2015
Curriculum Committee Chair (Clinical Research Training Program, Mayo Clinic)	2002 to 2006
Data Safety and Monitoring Board Member (Mayo Clinic Cancer Center)	2003 to 2006
Clinical Studies Oversight Committee Member (Mayo Clinic Cancer Center)	2003 to 2006
Neuro-Oncology Executive Committee Member (Mayo Clinic Cancer Center)	2003 to 2010
Neuro-Oncology Protocol Planning Committee Member (Mayo Clinic Cancer Center)	2003 to 2007
Education Committee Member (Mayo Graduate School)	2004 to 2006
Executive Committee Member (Department of Health Sciences Research, Mayo Clinic)	2004 to 2008
Education Programs Curriculum Committee Member (Center for Translational Activities, Mayo Clinic)	2006 to 2008
Division Chair (Division of Biostatistics, Health Sciences Research, Mayo Clinic)	2006 to 2008
Peer Review Research Committee Member (Department of Surgery, Mayo Clinic)	2011 to 2015
Research Executive Committee Member (Department of Surgery, Mayo Clinic)	2011 to 2015

Research Committee Member (Department of Surgery, Mayo Clinic)	2011 to 2015
Data Safety and Monitoring Board Member (Department of Surgery, Mayo Clinic)	2012 to 2015
Division Chief for Healthcare Policy & Research	2015 to present
Healthcare Policy & Research Promotions Committee Member	2015 to present
Weill Cornell Medicine Data Safety and Monitoring Board (alternative) Co-Chair	2017 to present
Weill Cornell Committee of Review	2018 to present

I. RESEARCH SUPPORT

Summarize **Past Research** Support:

1. The Mayo Clinic Research Training Program funded by National Center for Research Resources (K30 RR 22296) from 06/1999 to 09/206 ; role: Associate Director
2. Risk Factors for Venous Thromboembolism in the Community funded by NHLBI (R01 HL 66216) from 04/2001 to 04/2005; role: Co-investigator
3. Angiotensin-II Blockade in Mitral Regurgitation funded by NHLBI (R01 HL 64928) fron 04/2001 to 03/2005; role: Co-investigator
4. Core 1: Statistical and Administrative Core in: Gene Therapy for Vaso-occlusive disease funded by NHLBI (P01 HL 66958) from 09/2001 to 08/2008; role: Co-investigator 5. Core B: Study Design and Analysis Core in: Molecular Markers of Glioma Initiation & Progression funded by NCI (P01 CA 85799) from 06/2001 to 05/2006; role: Principal Investigator
6. GSK-3 and Associated Pathways in PNET funded by NINDS (R01 NS 40794) from 07/2002 to 11/2005; role: Collaborator
7. Mitochondria and surgical myopreservation in aging funded by NIA (R01 AG 21201) from 09/2002 to 08/2008; role: Consultant
8. Heart Failure in the Community funded by NHLBI ((R01 HL 72435) from 01/2003 to 06/2007; role: Co-investigator
9. Flavopiridol as a Potential Therapy in Multiple Myeloma funded by NCI (R01 CA 98118) funded from 07/2003 to 06/2008; role: Co-investigator
10. MAGE-A3/HPV 16 Peptide Vaccines for Head and Neck Cancer funded by the NIDCR (R01 DE 15324) from 04/2004 to 12/2004; role: Co-investigator
11. Xenograft Model for Studying Amplified EGFR in GBM funded by NCI (R01 NS 49720) from 08/2004 to 05/2006; role: Co-investigator
12. Brain Tumor SPORE – Core B – Biostatistics funded by NCI (P50CA 108961) from 09/2004 to 08/2014; role: Core Director
13. Global Differential Expression Profiling During Sudden Tumor Progression Using the Tumor Dedifferentiation Phenomenon as a Model funded by Mayo Clinic Foundation (CR20) from 04/2006 to 06/2010; role: Co-investigator
14. Measles Virotherapy for Glioblastoma Multiforme funded by NCI (R21 CA 123839) from 08/2006 to 07/2010; role: Co-investigator
15. Utility of Serum and Tissue Biomarkers for Predicting Response to Androgen Deprivation Therapy in the Population of Men with Rising PSA Following Definitive Treatment in: SPORE in Prostate Cancer funded by NCI (P50 CA 91956) from 09/2006 to 08/2013 ; role: Co-investigator
16. SPORE in Prostate Cancer—Biostatistics Core funded by NCI (P50 CA 91956) from 09/2006 to 08/2013; role: Core Director
17. Statistical Responsibilities for American College Of Surgical Oncology Group (ACOSOG) funded by NCI (U10 CA 76001) with subcontract to Mayo from 03/2006 to 11/2014; role: Principal Investigator
18. Epigenetic regulation of temozolomide responsiveness in glioblastoma funded by NCI (R01 CA 127716) from 01/2008 to 12/2012; role: Co-Investigator
19. Correlative Science and Imaging Analysis for Z1031 funded by Breast Cancer Research Foundation (WU-09-200) with subcontract to Mayo fro m10/2008 to 09/2009; role: Principal Investigator
20. A phase III randomized Double Blind study of Adjuvant ST1571 (Gleevee) versus Placebo in patients following the Resection of primary gastrointestinal Stromal Tumor (GIST) funded by Novartis from 12/2008 to 06/2009; role: Principal Investigator
21. Mayo Comprehensive Cancer Center Grant funded by NCI (P30CA 15083) from 03/2009 to 07/2015; role: Statistician
22. Novel Biomarkers for Aromatase Inhibitor Therapy funded by NCI (R01 CA 95614) from 04/2009 to 12/2011;

role: Principal Investigator
23. Optimizing Measles Virotherapy in the Treatment of Gliomas funded by NCI (R01CA 140620) from 07/2009 to 03/2011; role: Co-investigator
24. ACOSOG Community Clinical Oncology Program (CCOP) Research Base funded by NCI (U10CA 149950) from 06/2010 to 07/2014; role: Co-investigator
25. Treatment patterns of patients with newly diagnosed malignant primary brain tumors funded by Monteris Medical from 09/2010 to 08/2011; role: Principal Investigator
26. Statistical Responsibilities for American College Of Surgical Oncology Group (ACOSOG) in: Industry Supplement of Statistical Responsibilities for American College Of Surgical Oncology Group (ACOSOG) funded by Duke Clinical Research Institute from 12/2010 to 11/2011; role: Principal Investigator
27. N1037 P95HER2 expression in metastatic breast cancer patients treated with trastuzumab on N0337 and NCCTG 98-32-52 funded by BioTheranostics/BioMerieux from 10/2011 to 3/2012; role: Co-investigator
28. Part 1 N9831F-NCCTG-ICSC Validation study of Quantitative Single Gene Assessment of HER2 mRNA by qRT-PCR and Development and Testing of New HER2 Multi-Gene Signature funded by Genomic Health, Inc. from 04/2012 to 05/2015; role: co-Principal Investigator
29. Therapeutic Strategy to Slow Progression of Calcific Aortic Valve Stenosis funded by National Center for Advancing Translational Sciences (UH2TR 000954) fro 06/2013 to 07/2015; role: Co-investigator
30. Patient Centered: Risk Stratified Surveillance After Curative Research of Colorectal Cancer funded by a subcontract from a PCORI grant (CE-1304-6855) from 03/2014 to 07/2015; role: Principal Investigator
31. Post-Treatment Surveillance in Breast Cancer: Bringing CER to the Alliance funded by a subcontract from a PCORI grant (CE-1304-6543) from 03/2014 to 07/2015; role: Principal Investigator
32. Statistics and Data Center for the Alliance for Clinical Trials in Oncology funded by NCI (U10CA 180882) from 04/2014 to 07/2015; role: Co-investigator
33. Alliance NCORP Research Base funded by NCI (UG1CA 189823) from 08/2014 to 07/2015; role: Co-investigator
34. Improving How We Predict Toxicity for Older Women with Breast Cancer funded by Susan G. Komen Breast Cancer Foundation from 10/2014 to 09/2017; role: Principal Investigator (subsite)
35. Sarcoma Foundation from 11/2015 to 05/2017; role: Principal Investigator
36. Clinical and Translational Science Center (2UL1 TR000457) funded by NIH from 06/01/12 to 05/31/17; role: Co-Investigator
37. SPECs Grant in Lung Cancer (U01CA 157715) funded by NCI from 07/2012 to 06/2018; role: PI of a subcontract
38. Sarcoma SPORE—Biostatistics Core funded by NCI (5U54CA 168512) from 09/2016 to 08/2018; role: Core Director
39. Prostate Cancer Foundation study funded from 07/2017 to 08/2018; role: co-investigator

For **Current extramural and intramural research funding**, provide the following for each award:

1. Source, amount, and duration of support (dates)
2. Name of Principal Investigator
3. Individual's role in project, including percentage (%) effort

Current Research Support (duplicate table as needed):

Source	NCI (CA180882) subcontract Alliance
Amount	$172029
Duration	04/2018 to 02/2023
Principal Investigator	Mandrekar
Your Role in Project	Co-investigator (PI of the subcontract to WCMC)
% Effort	40%

Source	SU2C
Amount	$13,515
Duration	08/2017 – 06/2020

Principal Investigator	Cantley
Your Role in Project	Co- Investigator
% Effort	5%

Source	National Institutes of Health 1UL1TR002384-01
Amount	$5,319,707
Duration	09/2017 to 06/2022
Principal Investigator	Imperato-Mcginley
Your Role in Project	Co-Investigator
% Effort	6%

Source	Department of Defense (Subcontract with Duke University, W81XWH-17-1-0372)
Amount	$170,266
Duration	11/2017 to 10/2020
Principal Investigator	Harpole
Your Role in Project	Principal Investigator (Subsite)
% Effort	10%

Source	National Institutes of Health (P50 CA211024-01A1)
Amount	$134,759
Duration	07/2017 to 06/2022
Principal Investigator	Rubin
Your Role in Project	Computational Biology and Biostatistics Core Director
% Effort	3%

Source	Bill and Melinda Gates Foundation
Amount	$89,116
Duration	11/2016 to 05/2020
Principal Investigator	Lee
Your Role in Project	Investigator
% Effort	2%

Source	NIMH, ALACRITY for late- and Mid-Life Mood Disorders (P50 MH113838)
Amount	$1,014,850
Duration	09/2016 to 08/2021
Principal Investigator	Alexopoulos
Your Role in Project	Investigator
% Effort	5%

Source	NIH, Biomarkers of taxane chemotherapy response/resistance in prostate cancer (R21 CA216800-01A1)
Amount	$130,500
Duration	04/2018 to 03/2020
Principal Investigator	Giannakakou
Your Role in Project	Investigator
% Effort	2%

Source	Department of Defense, Molecular and clinical correlates with prostate-specific membrane antigen (PSMA)-targeted radionuclide therapy (W81XWH-17-PCRP-IA)
Amount	$72,380
Duration	07/2018 to 06/2021
Principal Investigator	Tagawa/Beltran/Bander
Your Role in Project	Investigator
% Effort	2%

Source	NIH/NCI, Mechanism-based Targeting of Mantle Cell Lymphoma (P01 CA2144274-01A1)
Amount	$1,166,145
Duration	09/2018 to 08/2023
Principal Investigator	Chen-Kiang
Your Role in Project	Core Leader
% Effort	8%

Source	NIH, The human distal airway aging project (U01HL145561)
Amount	$5,688
Duration	01/19-12/2024
Principal Investigator	Shaykhiev
Your Role in Project	Biostatistician
% Effort	3%

J. EXTRAMURAL PROFESSIONAL RESPONSIBILITIES

i.e. – Journal Reviewer, Editorial Boards, Study Sections, Invited Presentations

Activity / Responsibility	Dates
Reviewer The American Math Monthly	1991 to 1999
Gender and Ethnic Division Committee Member North Central Cancer Treatment Group	2002 to 2005
Neuro-Oncology Committee Member North Central Cancer Treatment Group	2002 to 2006
Reviewer The American Statistician	1994 to 1999
Editorial board member Journal of Statistics Education	1998 to 2003
Reviewer Mayo Clinic Proceedings	2001 to 2004
Reviewer Circulation	2003 to 2006
NCI Review Panel Member Consortium Therapeutic Studies of Primary Central Nervous System Malignancies in Adults	2003, 2008
Reviewer Bioinformatics	2004 to present
NCI Study Section ad hoc Member Scientific Review Group Subcommittee H-Clinical	2004, 2007, 2008
Reviewer Cancer Research	2004 to present

Editorial Board Neuro-Oncology	2005 to 2014
Reviewer American Journal of Gastroenterology	2005 to 2006
Review Panel Member Academic Public-Private Partnership Program (AP4)	2005
NCI-Avon Foundation Review Panel Member PFP Awards Program	2005 to 2006
NCI Review Panel Member Advanced Proteomic Platforms and Computation Sciences for the NCI Clinical Proteomic Technologies Initiative Review Panel	2006
Executive Committee Member American College of Surgeons Oncology Group	2006 to 2012
NCI Committee Member Breast Cancer Intergroup Committee	2007 to 2009
NCI Committee Member Breast Cancer Intergroup Correlative Sciences Committee	2008 to 2009
NCI Study Section Member Scientific Review Group Subcommittee H-Clinical	2009 to 2012
NCI Steering Committee Member Gastrointestinal Stromal Tumor Working Group	2009 to 2013
NCI Steering Committee Member Brain Malignancies	2009 to present
NCI Review Panel Member Novel Methodologies	2006
Data Monitoring Committee Member American College of Surgeons Oncology Group	2006 to 2011
Breast Cancer Committee Lead Statistician American College of Surgeons Oncology Group	2006 to 2011
Reviewer Biometrics	2006
NIAID Review Panel Member Cooperative Study Group for Autoimmune Disease Prevention	2006
Clinical Scientific Review Committee Member American College of Surgeons Oncology Group	2006 to 2011
Reviewer International Journal of Cancer	2006 to present
NICHHD Review Panel Member Obstetrical Pharmacology Research Network-Data Coordination and Analyses Center (OPRU-DCAC)	2007
Canada Cancer Society Review Panel Grant Application Review	2007
Editorial Board Journal of Clinical Oncology	2007 to 2010
NIAID Review Panel Member Proteomics Centers for Infectious Diseases and Biodefense	2008
NIDDK Review Panel Member Hepatitis B Clinical Research Network (U01)	2008
NIH Review Panel Member Data Management and Coordinating Center DMCC for the Rare Diseases Clinical Research Network (RDCRN)	2008
NIDDK Review Panel Member Multi-disciplinary Approach to the Study of Chronic Pelvic Pain (MAPP) Research Network (U01)	2008
Data Monitoring Committee Member Astra-Zeneca Phase III Trial	2008 to 2012
Reviewer EURASIP Journal on Bioinformatics and Systems Biology	2008 to present
NCI Committee Member	2008 to 2009

Clinical Trials Advisory Committee, Operational Efficiencies Working Group	
NICHHD Review Panel Member Best Pharmaceuticals for Children Act Data Coordinating Center	2009
MN Partnership for Biotechnology and Medical Genomics Review Panel Member Scientific review of grant proposals	2009
NIDA Review Panel Member Data and Statistics Center for NIDA Clinical Trials Network	2009
Thoracic Cancer Committee Lead Statistician American College of Surgeons Oncology Group	2009 to 2011
Reviewer British Journal of Cancer	2009 to present
Reviewer Clinical Trials	2009 to present
Reviewer Plos1	2009 to present
NCI Review Panel Member Clinical Proteomic Technologies for Cancer Initiative: Proteome Characterization Centers	2010
NICHHD Review Panel Member Pediatric Trials Network	2010
Review Panel Member National Cancer Institute of Canada	2010
DOD CDMRP Review Panel Member	2010 to 2019
Data Monitoring Committee Chair University of Minnesota Iron Study	2010 to 2014
Data Monitoring Committee Member Eli Lilly 14T-MC-JVBB Trial	2010 to 2014
Data Monitoring Committee Incyte RESPONSE Trial	2010 to 2014
Associate Editor Journal of Clinical Oncology	2010 to 2017
Deputy Editor Journal of Clinical Oncology	2017 to present
Reviewer Nature	2010, 2013, 2017, 2018
NICHHD Review Panel Member Systematic Review of Neonatal Medicine	2011
NICHHD Review Panel Member Maintenance of Child Health and Development Studies Name and Address Files	2011
Dutch Cancer Society Review Panel Member Scientific Grant Review	2011, 2014, 2015
Reviewer Annals of Surgery	2011 to present
Operations Committee Member Alliance Adult Cancer Cooperative Group	2011 to 2015
Scientific Concept Peer Review Committee Member Alliance Adult Cancer Cooperative Group	2011 to 2014
Data Safety Monitoring Board Chair Kanas University PAD in AA Trial	2011 to 2018
NICHHD Review Panel Member Folic Acid Supplementation and Semen Quality Trial (FAAST)	2012
NIAID Review Panel Member Pre-Clinical Pharmacology and Toxicology Studies	2012
NCI Review Panel Pre-clinical Efficacy and Intermediate Endpoint	2012
NIDA Review Panel Data, Statistics, and Clinical Trial Support for NIDA	2012, 2014
Cancer in the Elderly Committee Lead Statistician Alliance Adult Cancer Cooperative Group	2012 to 2015

NICHHD Review Panel Member Multiple Study Data Coordinating Center for DESPR	2013
Mayo Clinic Review Panel Member Microbiome Program Clinic Trial Funding	2013
NICHHD Review Panel Member Further Investigation into the Causes of Stillbirth Concept Clearance	2013
Publications Committee Member Alliance Adult Cancer Cooperative Group	2013 to 2016
Neuro-Oncology Committee Lead Statistician Alliance Adult Cancer Cooperative Group	2013 to present
FDA Medical Devices Advisory Committee Member General and Plastic Surgery Devices	2013 to present
Damon Runyon Foundation Review Panel Member Clinical Investigator Award	2013 to present
NCI Brain Malignancies Steering Committee member	2013 to present
NCI Review Panel Member PLCO Secondary Studies Proposals	2014, 2015
NIAID Review Panel Member Inner City Asthma Consortium (ICAC3)	2014
Associate Editor Neuro-Oncology	2014 to 2018
Data Safety and Monitoring Board Committee Member NIDDK	2014 to present
NICHHD Review Panel Member P01 Pre-Natal Microbiome Grant Review	2015
NIAID Review Panel Member Centers for Medical Countermeasures against Radiation Consortium (U19	2015
Cancer Research UK Review Panel Member Biomarker Project Award	2015
Statistical Associate Editor American Journal of Respiratory and Critical Care Medicine	2015 to present
Independent Data Monitoring Committee Member Ariad Phase II trial of AP26113 in non-small cell lung cancer	2015 to 2018
NIAMS Technical Evaluation Panel Member Clinical Studies Management and Support	2016
NIAID Scientific Review Panel Member Asthma and Allergic Diseases Cooperative Research Centers	2016
NICHD Technical Evaluation Panel Member Best Pharmaceutical for Children Act Data Coordinating Center	2016
NINDS Scientific Review Panel Member Parkinson's Disease Biomarkers Program	2016
Cancer Research United Kingdom Review Panel Member Program Project Submission	2016
Data Safety and Monitoring Board Member The Comparison of Outcomes of Antibiotic Drugs and Appendectomy (CODA) Trial	2016 to present
United States Army Medical Research and Material Command (MRMC) Peer Review Panel Member	2016 to 2018
KNOD Study Section Committee Member	2018 to present
Cancer Moonshot Initiative: Human Tumor Atlas Research Centers (U2C) review panel member	2018
Clinical Research Training Institute Summer Workshop Faculty Member American Society of Hematology	2016 to present
Cancer LinQ Publications Committee Member	2016 to present
STATS.org Statistical Advisory Board Member	2016 to present
NIH/NIAID Asthma and Allergic Diseases Cooperative Research Centers	2017
NCI Program Project Grant (P01) Review Committee Member	2017
Data Safety and Monitoring Board Member	2017 to present

Clofazimine in the treatment of pulmonary Mycobacterium avium complex (MAC) disease trial	
NCI Oncology E Review Panel Member	2017
ASCO CancerLinQ Research and Publications Committee Member	2017 to present
Conquer Cancer Foundation Grant Selection Committee Member	2017 to present
Independent Data Monitoring Committee Member Takeda Phase III trial of brigatinib in non-small cell lung cancer	2018 to present
NCI Moonshot Initiative, the NCI Human Tumor Atlas Network (HTAN) Review Committee Member	2018
NCI Breast Cancer Steering Committee Member	2018 to present
NCI Program Project Grant (P01) Review V Committee Member	2019

K. PROFESSIONAL MEMBERSHIPS

Include medical and scientific societies

Member/Officer/Fellow/Role	Organization	Dates
Member	Operations Research Society of America	1990 to 1993
Officer	Operations Research Society of America	1992
Member	Mathematical Association of America	1991 to 1997
Officer	American Statistical Association	2000 to 2003; 2011 to 2013
Member	American Statistical Association	2000 to present
Member	American Society of Clinical Oncology	2005 to present
Member	Society of Neuro-Oncology	2007 to present
Member	International Biometric Society, East North American Region	2006 to present
Officer	International Biometric Society, East North American Region	2008 to 2011
Member	Society of Clinical Trials	2008 to present

L. HONORS AND AWARDS

Name of award	Date awarded
Pi Mu Epsilon (Math honorary) - Macalester College	1980
Phi Beta Kappa - Macalester College	1982
Magna Cum Laude - Macalester College	1983
Academic All-American, Division III Volleyball - Macalester College	1983
Fredrick Hennie II Teaching Award - Massachusetts Institute of Technology	1987
Health Sciences Research Distinguished Teaching Award - Mayo Clinic	2004
Macalester College Distinguished Alumni in Science	2015

M. BIBLIOGRAPHY

1. Articles in professional peer-reviewed journals

1. **Ballman KV**. Greater emphasis on variation in an introductory statistics course. J Statistics Education. 1997; 5(2).

2. Singh M, Nuttall GA, **Ballman KV**, Mullany CJ, Berger PB, Holmes DR Jr, Bell MR. Effect of abciximab on the outcome of emergency coronary artery bypass grafting after failed percutaneous coronary intervention. Mayo Clin Proc. 2001 Aug; 76(8):784-8. PMID:11499816. DOI:10.1016/S0025-6196(11)63221-7.

3. McConnell JP, Branum EL, **Ballman KV**, Lagerstedt SA, Katzmann JA, Jaffe AS. Gender differences in C-reactive protein concentrations - Confirmation with two sensitive methods. Clinical Chemistry & Laboratory Medicine. 2002; 40(1):56-9. PMID:11916271.

4. Aviles RJ, Wright RS, Aviles JM, McDonald F, **Ballman K**, Harker-Murray A, Scott C, Lauer MS, Kopecky SL, Jaffe AS. Long-term prognosis of patients with clinical unstable angina pectoris without elevation of creatine kinase but with elevation of cardiac troponin I levels. Am J Cardiol. 2002 Oct 15; 90(8):875-8. PMID:12372578.

5. Brilakis ES, McConnell JP, **Ballman KV**, Klee GG, Berger PB. Lack of association between plasma homocysteine and angiographic coronary artery disease in the era of fortification of cereal grain flour with folic acid. Atherosclerosis. 2002 Dec; 165(2):375-81. PMID:12417290.

6. Squires RW, Leung TC, Cyr NS, Allison TG, Johnson BD, **Ballman KV**, Wagner JA, Olson LJ, Frantz RP, Edwards BS, Kushwaha SS, Dearani JA, Daly RC, McGregor CG, Rodeheffer RJ. Partial normalization of the heart rate response to exercise after cardiac transplantation: frequency and relationship to exercise capacity. Mayo Clin Proc. 2002 Dec; 77(12):1295-300. PMID:12479515. DOI:10.4065/77.12.1295.

7. Leung TC, **Ballman KV**, Allison TG, Wagner JA, Olson LJ, Frantz RP, Edwards BS, Dearani JA, Daly RC, McGregor CG, Rodeheffer RJ. Clinical predictors of exercise capacity 1 year after cardiac transplantation. J Heart Lung Transplant. 2003 Jan; 22(1):16-27. PMID:12531409.

8. Weisberg IS, Park E, **Ballman KV**, Berger P, Nunn M, Suh DS, Breksa AP, Garrow TA, Rozen R. Investigations of a common genetic methyltransferase (BHMT) variant in betaine-homocysteine in coronary artery disease. Atherosclerosis. 2003 Apr; 167(2):205-14. PMID:12818402.

9. O'Neill BP, Iturria NJ, Link MJ, Pollock BE, **Ballman KV**, O'Fallon JR. A comparison of surgical resection and stereotactic radiosurgery in the treatment of solitary brain metastases. Int J Radiat Oncol Biol Phys. 2003 Apr 1; 55(5):1169-76. PMID:12654423.

10. Takemoto Y, Tanabe K, Chandrasekaran KW, **Ballman KV**, Seward JB, Belohlavek M. Single-plane and biplane echocardiography: Use of targeted scan planes improves the estimates of left ventricular volume and shape for analysis of postinfarction remodeling. J Am Soc Echocardiogr. 2003 May; 16(5):448-56. PMID:12724654.

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APPENDIX B

MATERIALS RELIED UPON

Court Documents

Plaintiffs' Third Amended Medical Monitoring Class Action Complaint, *Valsartan Products Liability Litigation,* November 1, 2021.

Plaintiffs' Memorandum of Law in Support of the Medical Monitoring Plaintiffs' Motion for Class Certification, *Valsartan Products Liability Litigation*, November 10, 2021.

Expert Reports

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PRINSTON00075797

SOLCO00028261

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